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L4: Entry 94 of 103

File: USPT

Feb 4, 1992

DOCUMENT-IDENTIFIER: US 5085866 A

TITLE: Method of producing zero-order controlled-released devices

Brief Summary Text (5):

The intraoral fluoride-releasing devices described above are just one classic reservoir-type devices having zero-order (constant) release kinetics. Such devices obey Fick's Law of Diffusion because the rate of release of agent, such as fluoride, from the device varies directly with the surface area of the device and inversely with the thickness of the rate-controlling membrane. Because these devices typically deliver drugs, both the rate and the duration of release must be controlled precisely for maximum therapeutic effect with a minimum of toxicity.

Brief Summary Text (8):

Because the coating has to function as a rate-controlling membrane that obeys Fick's Law of Diffusion, it requires homogeneous, continuous coatings without either gross or micro defects. However, the currently used single solvent process does not provide Fickian membranes. In the current fluidized-bed processes, the solvent for the coating polymer must evaporate fast enough so that the surfaces of the cores never become sticky. If they become sticky, twinning (two fused cores) or gross agglomeration occurs. On the other hand, if the solvent evaporates too quickly, the polymer coating is deposited as discrete heterogeneous particles or flakes. Heterogeneous coatings do not obey Fick's Law of diffusion because the drug is released at a fast rate through discontinuities in the coating.

Detailed Description Text (8):

During coating, the plasticizing solvent remains in the deposited microdroplet while the fast-evaporating solvent evaporates, and the microdroplets fuse to form a continuous homogeneous membrane. For this reason, the temperature within the fluidized-bed apparatus should be as close as possible to, but not meeting or exceeding, the boiling point of the plasticizing solvent. The difference between the boiling points of the two solvents should also be as great as possible. Also, the temperature of the coating process should take into account the decomposition limits of the drug and polymer.

Detailed Description Text (10):

Any thermoplastic polymer or copolymer may be utilized in the present invention so long as it can be dissolved in the solvent and deposited onto the core. However, amorphous polymers are preferred over crystalline polymers. Examples of such polymers and copolymers include, among others, polymethyl methacrylate, polyhydroxyethyl methacrylate, poly (ethyl acrylate), cellulose acetate, ethyl cellulose, methyl cellulose, cellulose acetate-butyrate, hydroxypropyl cellulose, polyethylene, poly (ethylene-vinyl acetate), poly(ethylene-acrylic acid), polystyrene, polycarbonate, polyamides, poly(ethylene terephthalate), polyether-polyurethane and polyester-polyurethane block copolymers, and polyacetals. In some instances, the nature of the agent must be considered in choosing the polymer. For instance, a HEMA/MMA copolymer may be most useful with a water soluble or hydrophilic agent, while an ethylene/vinylacetate copolymer may be used with the lipophilic steroids and most other drugs. The primary consideration is that the agent must be diffusible through the polymeric coating.

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L4: Entry 68 of 103

File: USPT

Nov 10, 1998

DOCUMENT-IDENTIFIER: US 5834582 A

TITLE: Degradable polymer composition

Brief Summary Text (4):

Some polymers are known to degrade by hydrolysis in the presence of water and thereby decompose to smaller chemical units. Some of these polymers are also biodegradable, such as polylactic acid and polyglycolic acid. Due to the expense and difficulty in preparing these hydrolytically degradable polymers, their use has been largely confined to high value medical applications where bioabsorbable materials are required. Most reported medical applications involve internal use of the polymers, such as for sutures, prosthetic devices, and drug release matrices. Some polymers that have received considerable attention for medical applications include polylactic acid, polyglycolic acid, poly-e-caprolactone and polydioxanone.

Brief Summary Text (102):

Quenching to an amorphous state requires that the polymer or copolymer in an amorphous melt is rapidly cooled from its molten state to a temperature below its T.sub.g. Failure to cool rapidly allows spherulitic crystallinity to develop, that is, crystalline domains of submicron to micron size. The latter scatters light and the polymer specimens become opaque. These crystalline forms have improved stability to heat distortion. This spherulitic crystallinity is often called short range order-long range disorder since the crystallites are separated by amorphous regions. However, the crystallites act as pseudo crosslinks to maintain dimensional stability above the T.sub.g but below their melting points. Alternatively stability to heat distortion can be obtained by orienting an amorphous polymer above its T.sub.g but below its melting point. Here, the polymer molecules are stretched to allow some long range ordering, then "heat set" to permit the ordering to complete, that is, given some time to anneal. The amorphous polymer is thereby crystallized into a different order, called long-range order, short range disorder. Transparency and resistance to heat distortion are favored.

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